

EPA Registration Number
11556-117 vol. 2

Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

Reg. No. 11556-117

Send to SIG: check box ☒

This material is:

☒ New stamped-accepted label

☐ New CSF

☐ Notification

☐ Final Printed Label

☐ Other: _____

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: X. Q. B.

Phone: 306-0415 Division: RD

Date: 3-4-08



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Douglas A. Spilker
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

MAR 4 2008

Dear Dr. Spilker:

Subject: Labeling Amendment; Label Claim Revisions
Advantage 10 Topical Solution
EPA Registration No. 11556-117
Date Submitted: February 15, 2008

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable with the following provisions:

1. Revise the claim "*Kills 98-100% of the fleas on dogs within 12 hours*" to read "*Kills fleas on dogs within 12 hours.*"
2. On page 3 of the label, revise the sentence "*Treatment of pets with Advantage rapidly kills fleas and may reduce the incidence of this condition.*" to read "*Treatment of dogs with Advantage kills fleas and may reduce the incidence of this condition.*"
3. On page 4 of the label, revise the sentence "*Advantage kills 98-100% of the fleas on pets within 12 hours.*" to read "*Advantage kills fleas on dogs within 12 hours.*"

A stamped copy is enclosed for your records. Please submit one (1) final printed copy for the referenced label, incorporating the above changes, before releasing the product for shipment. If you have any questions regarding this letter, please contact me at (703) 306-0415.

Sincerely,

Kable Bo Davis
Entomologist
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

Note to Reviewer: [Brackets and parentheses indicate alternate language]

Advantage® 10
(imidacloprid) Topical Solution

Once-A-Month Topical Flea and Lice Treatment For [Small] Dogs and
Puppies 7 Weeks and Older and 10 lbs and Under.

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea and Lice Infestations on Dogs

- Available only through licensed practicing veterinarians
- One treatment prevents further flea infestation for at least four (4) weeks
- Kills 98-100% of the fleas on dogs within 12 hours
- Kills fleas before they lay eggs
- Convenient, easy to apply
- Kills [(biting) (chewing)] lice
- For treatment and prevention of [(biting) (chewing)] lice [infestations]
- Controls existing [(biting) (chewing)] lice infestations
- Dual protection (against fleas and lice)
- Treats, prevents and controls [(biting) (chewing)] lice [infestations]
- Provides effective control of [(biting) (chewing)] lice [infestations]
- Kills [(biting) (chewing)] lice and prevents further infestations
- For treatment and prevention of infestations with [(biting) (chewing)] lice
- Waterproof
- Fragrance free

	<u>% By Weight</u>
Active Ingredient	
Imidacloprid	9.1%
Other Ingredients	90.9%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

[For Directions For Use and other labeling, see supplemental labeling inside]

ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAR 4 2008

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
11556-117

WARNING

See Below for First Aid and Precautionary Statements

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS: Causes eye irritation. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling. Keep out of reach of children. Do not contaminate feed or food.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under seven weeks of age. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product. For consumer questions call 1-800-255-6826. For medical emergencies call 1-800-422-9874.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in eyes: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If swallowed: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

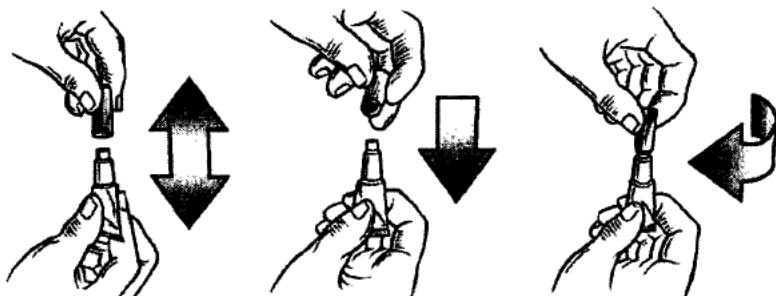
To Physician: Treat the patient symptomatically.

DIRECTIONS FOR USE

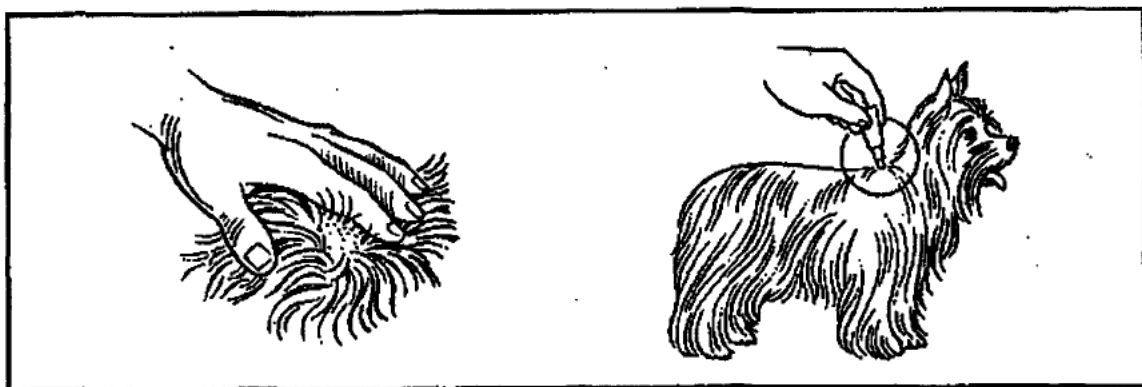
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HOW TO APPLY

1. Use only on dogs. Do not use on other animals.
2. Remove one applicator tube from the package.



3. Hold applicator tube in an upright position. Pull cap off tube.
4. Turn the cap around and place other end of cap back on tube.
5. Twist cap to break seal, then remove cap from tube.



6. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube twice to *expel the entire contents directly on the skin.*

Do not get this product in your pet's eyes or mouth.

7. Discard empty tube as described in Storage and Disposal.

The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with Advantage rapidly kills fleas and may reduce the incidence of this condition.

Advantage kills 98-100% of the fleas on pets within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for up to four (4) weeks. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.

Larval flea stages in the pet's surroundings are killed following contact with an Advantage treated pet.

Advantage is waterproof and remains efficacious following a shampoo treatment, swimming or after exposure to rain or sunlight.

Monthly treatments are required for optimal control and prevention of fleas.

If re-treatment becomes necessary earlier than four weeks, do not re-treat more than once weekly.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a cool, dry place.

Disposal: If empty: Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 1-800-422-9874 for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Four [or six] 0.014 fl. oz (0.4 mL) Tubes

EPA Est. 11556-DEU-1
EPA Reg. No. 11556-117

Manufactured For
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, Kansas 66201 USA

Made in Germany

[Label on Individual Tube]

Advantage® 10

9.1% Imidacloprid

0.014 fl. oz. (0.4 mL)

EPA Reg. No. 11556-117

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Bayer HealthCare LLC, Animal Health Div. POB 390, Shawnee Mission, KS 66201 [913-268-2751]	EPA Registration Number/File Symbol 11556-117
Active Ingredient(s) and/or representative test compound(s) Imidacloprid	Date 15 Feb 2008
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor, Non-food	Product Name Advantage 10 Topical Solution

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Douglas A. Spilker</i>	Date 15 Feb 2008	Typed or Printed Name and Title Douglas A. Spilker, EPA Reg. Affairs Manager
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Bayer HealthCare Animal Health

Via Federal Express



February 15, 2008

Document Processing Desk
(Fast Track Amendment – Non-PRIA Action)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Ms. Venus Eagle, PM Team 01
Registration Division

Subject: Label Amendments for Registration:

Advantage 9 Topical Solution (EPA Reg. No. 11556-116)
Advantage 10 Topical Solution (EPA Reg. No. 11556-117)
Advantage 18 Topical Solution (EPA Reg. No. 11556-118)
Advantage 20 Topical Solution (EPA Reg. No. 11556-119)
Advantage 55 Topical Solution (EPA Reg. No. 11556-120)
Advantage 100 Topical Solution (EPA Reg. No. 11556-122)

Bayer HealthCare LLC
Animal Health
P.O. Box 390
Shawnee Mission, KS 66201-0390

Dear Ms. Eagle:

Please find enclosed, for the Agency's review and acceptance, Applications for Amendment for Bayer HealthCare's currently registered subject products. Included with the respective applications are copies of the appropriate supporting documents and draft labeling. No data review is required to support these actions.

Bayer HealthCare, Animal Health Division, is proposing to revise the claims on the labels of its Advantage® products (EPA Reg. Nos. 11556-116, -117, -118, -119, -120, -120, and -122) to include the term "waterproof," the control of lice on the dog products, as well as make minor label updates and modifications as suggested by the Agency. An extra copy of each of the respective product draft labels has been highlighted to show the label changes. **No data are being submitted with these registration actions since all data required to support these revisions are on file with the Agency, and have already been reviewed and found acceptable by the Agency.** The respective studies being cited to support these revisions are listed in the individual applications, and also itemized in the updated data matrices for the products.

Since these label amendments require no data review, they should be categorized as "Registration actions that do not require the submission of registration service fees under the Pesticide Registration Improvement Renewal Act (PRIA 2)."

I hope this overview cover letter is helpful in processing the attached applications. If you have any questions, please do not hesitate to call me at (913) 268-2751.

Sincerely,



Douglas A. Spilker, Ph. D.
Manager, EPA Regulatory Affairs

DAS/lt

Enclosures:

1. Advantage 9 (EPA Reg. 11556-116)
 - a. Form 8570-1 Application for Amendment
 - b. Attachment to Application (2 pages)
 - c. Form 8570-1 Certification with Respect to Citation of Data
 - d. Letter of Authorization from Bayer CropScience
 - e. Data Matrix (CONFIDENTIAL), dated 02/15/2008
 - f. Data Matrix (PUBLIC), dated 02/15/2008
 - g. Draft Labels, dated 2/04/2008 (5 copies)
 - h. Draft Label (highlighted), dated 02/04/2008 (1 copy)
 - i. Email from George LaRocca [EPA] to Terry McNamara [Bayer AH], dated 01/28/2008
 - j. EPA Stamped-Accepted Labeling, acceptance date March 10, 2006
2. Advantage 10 (EPA Reg. 11556-117)
 - a. Form 8570-1 Application for Amendment
 - b. Attachment to Application (2 pages)
 - c. Form 8570-1 Certification with Respect to Citation of Data
 - d. Letter of Authorization from Bayer CropScience
 - e. Data Matrix (CONFIDENTIAL), dated 02/15/2008
 - f. Data Matrix (PUBLIC), dated 02/15/2008
 - g. Draft Labels, dated 2/04/2008 (5 copies)
 - h. Draft Label (highlighted), dated 02/04/2008 (1 copy)
 - i. Email from George LaRocca [EPA] to Terry McNamara [Bayer AH], dated 01/28/2008
 - j. EPA Stamped-Accepted Labeling, acceptance date March 10, 2006
 - k. Dog Lice efficacy review, dated 08/06/2007

3. Advantage 18 (EPA Reg. 11556-118)

- a. Form 8570-1 Application for Amendment
- b. Attachment to Application (2 pages)
- c. Form 8570-1 Certification with Respect to Citation of Data
- d. Letter of Authorization from Bayer CropScience
- e. Data Matrix (CONFIDENTIAL), dated 02/15/2008
- f. Data Matrix (PUBLIC), dated 02/15/2008
- g. Draft Labels, dated 2/04/2008 (5 copies)
- h. Draft Label (highlighted), dated 02/04/2008 (1 copy)
- i. Email from George LaRocca [EPA] to Terry McNamara [Bayer AH], dated 01/28/2008
- j. EPA Stamped-Accepted Labeling, acceptance date March 10, 2006

4. Advantage 20 (EPA Reg. 11556-119)

- a. Form 8570-1 Application for Amendment
- b. Attachment to Application (2 pages)
- c. Form 8570-1 Certification with Respect to Citation of Data
- d. Letter of Authorization from Bayer CropScience
- e. Data Matrix (CONFIDENTIAL), dated 02/15/2008
- f. Data Matrix (PUBLIC), dated 02/15/2008
- g. Draft Labels, dated 2/04/2008 (5 copies)
- h. Draft Label (highlighted), dated 02/04/2008 (1 copy)
- i. Email from George LaRocca [EPA] to Terry McNamara [Bayer AH], dated 01/28/2008
- j. EPA Stamped-Accepted Labeling, acceptance date March 10, 2006
- k. Dog Lice efficacy review, dated 08/06/2007

5. Advantage 55 (EPA Reg. 11556-120)

- a. Form 8570-1 Application for Amendment
- b. Attachment to Application (2 pages)
- c. Form 8570-1 Certification with Respect to Citation of Data
- d. Letter of Authorization from Bayer CropScience
- e. Data Matrix (CONFIDENTIAL), dated 02/15/2008
- f. Data Matrix (PUBLIC), dated 02/15/2008
- g. Draft Labels, dated 2/04/2008 (5 copies)
- h. Draft Label (highlighted), dated 02/04/2008 (1 copy)
- i. Email from George LaRocca [EPA] to Terry McNamara [Bayer AH], dated 01/28/2008
- j. EPA Stamped-Accepted Labeling, acceptance date March 10, 2006
- k. Dog Lice efficacy review, dated 08/06/2007

6. Advantage 100 (EPA Reg. 11556-122)

- a. Form 8570-1 Application for Amendment
- b. Attachment to Application (2 pages)
- c. Form 8570-1 Certification with Respect to Citation of Data
- d. Letter of Authorization from Bayer CropScience
- e. Data Matrix (CONFIDENTIAL), dated 02/15/2008
- f. Data Matrix (PUBLIC), dated 02/15/2008
- g. Draft Labels, dated 2/04/2008 (5 copies)
- h. Draft Label (highlighted), dated 02/04/2008 (1 copy)
- i. Email from George LaRocca [EPA] to Terry McNamara [Bayer AH], dated 01/28/2008
- j. EPA Stamped-Accepted Labeling, acceptance date March 10, 2006
- k. Dog Lice efficacy review, dated 08/06/2007

Advantage 10 Topical Solution
EPA Reg. No. 11556-117
 February 15, 2008

Attachment to:
 OPP APPLICATION FOR PESTICIDE – AMENDMENT

Section II – Explanation:

Bayer HealthCare, Animal Health Division, is proposing to revise the claims on the labels of its Advantage® products (EPA Reg. Nos. 11556-116, -117, -118, -119, -120, -120, and -122) to include the term “waterproof,” the control of lice on the dog products, as well as make minor label updates, and make modifications suggested by or permitted by the Agency. No data are being submitted with these registration actions since all data required to support these revisions are on file with the Agency, and have already been reviewed and found acceptable by the Agency. The respective studies being cited to support these revisions are listed in this application, and also itemized in the updated data matrix for the product.

Enclosed for the Agency’s acceptance are five (5) copies of the revised draft labels, dated February 4, 2008, for Advantage 10 Topical Solution, EPA Reg. No. 11556-117. Enclosed is an identical copy of the aforementioned draft label, with the respective revisions highlighted for the Agency’s convenience. The enclosed draft labeling (although in a slightly different format) is identical to the labeling accepted by the Agency on March 10, 2006 (copy enclosed), with the following changes:

- 1. The addition of label claims for control of dog lice (*Trichodectes canis*) in several appropriate places, as well as addition of several statements to call-out or clarify these claims to the customer.**

These claims are supported by efficacy data (Bayer Report No. 75950; MRID No. 47190401) previously submitted to and found acceptable by the Agency to support identical claims on other imidacloprid-containing products (Advantage Plus 10, EPA Reg. No. 11556-128; Advantage Plus 20, EPA Reg. 11556-125; Advantage Plus 55, EPA Reg. No. 11556-127; and Advantage Plus 100, EPA Reg. No. 11556-130). Please find enclosed a copy of the respective efficacy review, dated August 6, 2007. The reports are cited in the efficacy section of the enclosed data matrix.

- 2. Add the term “waterproof” in list of Marketing claims (bullets), as well as the appropriate place in the Directions for Use section.**

The current EPA Stamped Accepted label already has claims that “Advantage remains efficacious following a shampoo treatment, swimming or after exposure to rain or sunlight.” The aforementioned claim was accepted by the Agency based on the review and acceptance of Bayer Report No. 74792 (MRID No. 44256903), as listed in the data matrix. The enclosed revision of the current label is to add the term “waterproof” to further clarify to the customer the residual control of the product under these conditions. It is our understanding (see enclosed email from George LaRocca [EPA] to Terry McNamara [Bayer AH], dated 01/28/2008) that “...registrants may use the terms “waterproof”, “water repellent”, and “water resistant”, interchangeably provided the

Advantage 10 Topical Solution
EPA Reg. No. 11556-117
 February 15, 2008

bathing/washing studies were found acceptable.” Therefore, since we have an acceptable study on file, and the current label has claims similar in nature based on this study, we request the acceptance of the term “waterproof” to be used on the label.

3. Add Marketing claim to indicate that the product is “Fragrance free”

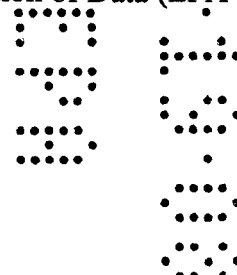
4. Make minor label modifications:

- a) Change emergency medical telephone number; the current number will remain in effect for an extended period of time to allow for channels-in-trade material to move appropriately through the system.
- b) Revise the Warranty Statement, revision based on responses we have received from the Agency in its review of other labels. The Warranty statement will include the phrase “TO THE EXTENT CONSISTENT WITH APPLICABLE LAW.”
- c) Revise the address block to include a more complete registrant address; revision based on guidance from EPA Website – “Pesticide Label Question & Answers, No. 14; Name & Address Issues.”
- d) Remove the scientific chemical name for imidacloprid in the ingredient statement; this revision is permitted per Label Review Manual (Page 5-3).

DATA COMPENSATION

An appropriate data matrix listing all of the data necessary to support the registration of the Advantage® products (EPA Reg. Nos. 11556-117, -119, -120, and -122) is enclosed with this application. A public version of the data matrix is also enclosed

All of the imidacloprid data supporting these applications are the property of Bayer Corporation. All of the data have either been previously submitted under EPA company number 264 (nee 3125) or have previously been submitted by the Animal Health Division (EPA company number 11556) of the Bayer HealthCare LLC. Accordingly, enclosed is a copy of Letter of Authorization from Bayer CropScience (EPA Company No. 264) authorizing the use of the generic imidacloprid data by Bayer HealthCare LLC, Animal Health Division (EPA Company No. 11556). These generic data are cited in the enclosed data matrix. A copy of a Completed Certification With Respect to Citation of Data (EPA Form 8570-34) is also enclosed.



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-117	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Advantage 10 Topical Solution	PM# Team 1	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P. O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Enclosed for Agency acceptance are 5 copies of the draft labeling, text dated 02/04/08, amended to add "waterproof" term, lice claim and make other minor changes. Please see attached for further information. There are no data to review, so this is a Non-PRIA action.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> Text <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Douglas A. Spilker, Ph. D.	Title Manager, EPA Regulatory Affairs	Telephone No. (Include Area Code) 913-268-2751
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager, EPA Regulatory Affairs	
4. Typed Name Douglas A. Spilker, Ph. D.	5. Date 15 Feb 2008	

Bayer CropScience



February 13, 2008

Document Processing Desk
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

Attention: Ms. Venus Eagle (PM 01, RD)

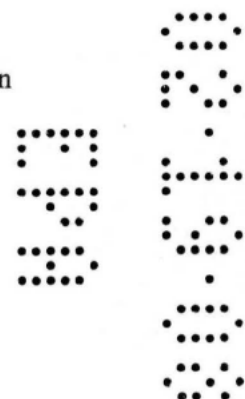
**Re: Letter of Authorization: Imidacloprid
Bayer HealthCare LLC, Animal Health Division (BHC) –
Advantage® Application for Registration**

Dear Ms. Eagle,

Bayer CropScience LP (BCS) hereby authorizes the Agency to refer to any research and/or test data on our active ingredient imidacloprid (the active ingredient in ADMIRE® and PROVADO®) in support of the applications for registration of **Advantage® 9** (EPA Reg. #: 11556-116), **Advantage® 10** (EPA Reg. #: 11556-117), **Advantage® 18** (EPA Reg. #: 11556-118), **Advantage® 20** (EPA Reg. #: 11556-119), **Advantage® 55** (EPA Reg. #: 11556-120) and **Advantage® 100** (EPA Reg. #: 11556-122), submitted by Bayer HealthCare LLC, Animal Health Division (BHC), P.O. Box 390, Shawnee Mission, KS, 66201-0390.

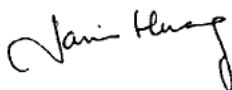
Furthermore, BCS and BHC are wholly owned subsidiaries of Bayer Corporation. Both companies seek product registrations for products containing the active ingredient imidacloprid. Any confidential business information released by the Agency in data evaluation records or other documents for company number 264 can be disclosed without restriction to the BHC, company number 11556. In addition, the Agency is authorized to refer to any research and/or test data submitted under company number 264 in support of applications for registration from Bayer HealthCare LLC, Animal Health Division (BHC), company number 11556.

Bayer CropScience
2 T.W. Alexander Drive
P. O. Box 12014
Research Triangle Park,
NC 27709
Tel: 919 549-2000



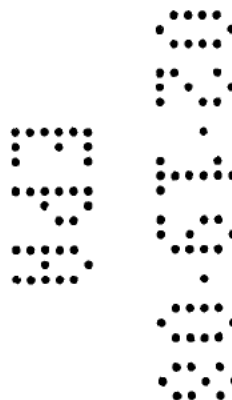
Please contact me at jamin.huang@bayercropscience.com or at 919-549-2634 if you have any questions regarding this submission.

Sincerely,



Jamin Huang, Ph.D.
Product Registration Manager

CC: Doug Spilker, Ph.D., Bayer HealthCare LLC, Animal Health Division





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401 M Street, S.W.
WASHINGTON, D.C. 20460 Form

Approved OMB No. 2070-0060

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DATA MATRIX

Date: February 15, 2008		EPA Reg No./File Symbol: 11556-117 11556-120 11556-119 11556-122		Page 1 of 10	
Bayer HealthCare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390		Product: Advantage® 10 Advantage® 20 Advantage® 55 Advantage® 100		Ingredient: Imidacloprid, CAS = 138261-41-3	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Report Number

Product Chemistry, Section 158.240

61-1	Chemical identity	42055302	264	PER	BR 1759 (TGAI)	
		43306001	264	PER	BR 1879 (TGAI)	
		43679611	11556	OWN	Report No. 74594 (Formulation)	
61-2	Statement of Composition	42055302	264	PER	BR 1759 (TGAI)	
		43306001	264	PER	BR 1879 (TGAI)	
		42270801	264	PER	BR 1785 (TGAI)	
61-3	Formation of impurities	43679611	11556	OWN	Report No. 74594 (Formulation)	
		42055302	264	PER	BR 1759 (TGAI)	
		43679611	11556	OWN	Report No. 74594 (Formulation)	
62-1	Preliminary analysis	42055303	264	PER	BR 1760 (TGAI)	
		43306002	264	PER	BR 1880 (TGAI)	
		42270802	264	PER	BR 1786 (TGAI)	
62-2	Certification of limits	43679612	11556	OWN	Report No. 74593 (Formulation)	
		42055303	264	PER	BR 1760 (TGAI)	
		43306002	264	PER	BR 1880 (TGAI)	
62-3	Analytical method	43679611	11556	OWN	Report No. 74594 (Formulation)	
		42055303	264	PER	BR 1760 (TGAI)	
		43213001	264	PER	BR 1874 (TGAI)	
		43306002	264	PER	BR 1880 (TGAI)	
		43679611	11556	OWN	Report No. 74594 (Formulation)	



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Bayer HealthCare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390		Product: Advantage® 10 Advantage® 20 Advantage® 55 Advantage® 100		Ingredient: Imidacloprid, CAS = 138261-41-3	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Report Number
					Description

63-1	Chemical and Physical Properties	42055304	264	PER	BR 1761 (TGAI)	
		43679611	11556	OWN	Report No. 74594 (Formulation)	
63-2	Appearance	42055304	264	PER	BR 1761 (TGAI)	
		43679611	11556	OWN	Report No. 74594 (Formulation)	
63-3	Physical state	42055304	264	PER	BR 1761 (TGAI)	
		43679611	11556	OWN	Report No. 74594 (Formulation)	
63-4	Odor	42055304	264	PER	BR 1761 (TGAI)	
		43679611	11556	OWN	Report No. 74594 (Formulation)	
63-5	Melting point	42055304	264	PER	BR 1761 (TGAI)	
63-6	Boiling point	42055304	264	PER	BR 1761 (TGAI)	
63-7	Density	42055304	264	PER	BR 1761 (TGAI)	
		43679611	11556	OWN	Report No. 74594 (Formulation)	
63-8	Solubility	42055304	264	PER	BR 1761 (TGAI)	
63-9	Vapor pressure	42055304	264	PER	BR 1761 (TGAI)	
63-10	Dissociation constant					N.A. - Does not dissociate
63-11	Octanol/water partition	42055304	264	PER	BR 1761 (TGAI)	
63-12	pH	42055304	264	PER	BR 1761 (TGAI)	
		43679611	11556	OWN	Report No. 74594 (Formulation)	
63-13	Stability	42055304	264	PER	BR 1761 (TGAI)	
63-14	Oxidizing/reducing action		264	PER		N.A. - No oxidative or reductive characteristics
63-15	Flammability	42055304	264	PER	BR 1761 (TGAI)	



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Bayer HealthCare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390		Product: Advantage® 10 Advantage® 20 Advantage® 55 Advantage® 100		Ingredient: Imidacloprid, CAS = 138261-41-3		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note Report Number	Description

63-16	Explodability	42055304	264	PER	BR 1761 (TGAI)	
		42055304	264	PER	BR 1761 (TGAI)	
63-17	Storage stability	43679611	11556	OWN	Report No. 74594 (Formulation)	
63-18	Viscosity					N.A. - Solid
63-19	Miscibility					N.A. - Solid
		42055304	264	PER	BR 1761 (TGAI)	
63-20	Corrosion characteristics	43679611	11556	OWN	Report No. 74594 (Formulation)	
63-21	Dielectric breakdown volt					N.A. - Solid
64-1	Submittal of samples				Samples available upon request	
Wildlife and Aquatic Organisms, Section 158.490						
71-1	Acute avian oral - quail/duck					N.A.
71-2(a)	Avian dietary - quail					N.A.
71-2(b)	Avian dietary - duck					N.A.
71-3	• Wild mammal toxicity					N.A.
71-4(a)	• Avian reproduction - quail					N.A.
71-4(b)	• Avian reproduction - duck					N.A.
71-5	Simulated or actual field study					N.A.
72-1(a)	Fish toxicity - bluegill					N.A.
72-1(b)	• Fish toxicity bluegill - lep					N.A.
72-2(a)	• Invertebrate toxicity - Daphnia					N.A.
72-2(b)	Invertebrate toxicity - Amphipods					N.A.



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Bayer HealthCare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390		Product: Advantage® 10 Advantage® 20 Advantage® 55 Advantage® 100		Ingredient: Imidacloprid, CAS = 138261-41-3		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note Report Number	Description

72-2(c)	Acute aquatic invertebrate toxicity - Chironomids					N.A.
72-3(a)	Estuarine / marine toxicity - fish					N.A.
72-3(b)	Estuarine / marine toxicity - mollusk					N.A.
72-3(c)	Estuarine/marine toxicity - shrimp					N.A.
72-4(a)	Early life stage - fish					N.A.
72-4(b)	Life cycle invertebrate					N.A.
72-7	Simulated or actual field study					N.A.
None	Foliar half-life and distribution for potatoes					N.A.
None	Runoff and Erosion predictions for apple/potato/cotton					N.A.
None	Risk assessment for apple/potato/cotton					N.A.
None	PELMO Modeling - sugarbeet/Germany					N.A.

Toxicology, Section 158.340

81-1		42055331	264	PER	Report No. 100040 (TGAI)	
		42256313	264	PER	Report No. 100010 (2 F)	
		43428201	264	PER	Report No. 106380 (1.6 F)	
		43679601	11556	OWN	Report No. 74585	
81-2		42055332	264	PER	Report No. 100041 (TGAI)	
		42256315	264	PER	Report No. 100002 (2 F)	
		43428201	264	PER	Report No. 106380 (1.6 F)	
		4379602	11556	OWN	Report No. 74584	



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Bayer HealthCare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390		Product: Advantage® 10 Advantage® 20 Advantage® 55 Advantage® 100		Ingredient: Imidacloprid, CAS = 138261-41-3	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Report Number

81-3	Acute inhalation toxicity, rat	42055333	264	PER	Report No. 99806 (TGAI)	
		42286101	264	PER	Report No. 99806-1 (TGAI)	
		42256317	264	PER	Report No. 100012 (2 F)	
		43428201	264	PER	Report No. 106380 (1.6 F)	
		43679603	11556	OWN	Report No. 74589	
81-4	Primary eye irritation - rabbit	42055334	264	PER	Report No. 99679 (TGAI)	
		42256319	264	PER	Report No. 99815 (2 F)	
		43428201	264	PER	Report No. 106380 (1.6 F)	
		43428201	264	PER	Report No. 106380 (1.6 F)	
		43679604	11556	OWN	Report No. 74588	
81-5	Primary dermal irritation - rabbit	42055335	264	PER	Report No. 99804 (TGAI)	
		42256321	264	PER	Report No. 99816 (2 F)	
		43428201	264	PER	Report No. 106380 (1.6 F)	
		43679605	11556	OWN	Report No. 74586	
81-6	Dermal sensitization - guinea pig	42055336	264	PER	Report No. 99800 (TGAI)	
		42256323	264	PER	Report No. 100003 (2 F)	
		43428201	264	PER	Report No. 106380 (1.6 F)	
		43679606	11556	OWN	Report No. 74587	
81-8(SS)	Acute neurotoxicity	43170301	264	PER	Report No. 106348	
		43285801	264	PER	Report No. 106348-1	
		42770301	264	PER	Report No. 103979	



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Bayer HealthCare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390			Product: Advantage® 10 Advantage® 20 Advantage® 55 Advantage® 100		Ingredient: Imidacloprid, CAS = 138261-41-3	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	Description
					Report Number	

82-1(a)	90-day feeding - rodent	42256327	264	PER	Report No. 100036	
82-1(b)	90-day feeding - non-rodent	42256328	264	PER	Report No. 100176	
82-2	21-day dermal - rabbit/rat	42256329	264	PER	Report No. 100688	
82-5(b)	90 day neurotoxicity - mammal	43286401	264	PER	Report No. 106356	
83-1(a)	Chronic feeding toxicity - rodent	42256331	264	PER	Report No. 100652	
		42256332	264	PER	Report No. 101931	
		42256333	264	PER	Report No. 102658	
		42256334	264	PER	Report No. 99672	
83-1(b)	Chronic feeding toxicity - non-rodent	42273002	264	PER	Report No. 100015	
83-2(a)	Oncogenicity - rat	42256331	264	PER	Report No. 100652	
		42256332	264	PER	Report No. 101931	
		42256333	264	PER	Report No. 102658	
		42256334	264	PER	Report No. 99672	
83-2(b)	Oncogenicity - mouse	42256335	264	PER	Report No. 100693	
		42256336	264	PER	Report No. 101929	
		42256337	264	PER	Report No. 99808	
83-3(a)	Developmental toxicity - rat	42256338	264	PER	Report No. 98571	
83-3(b)	Developmental toxicity - rabbit	42256339	264	PER	Report No. 98572	
83-4	Two generation reproduction - rat	42256340	264	PER	Report No. 100647	



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Bayer HealthCare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390		Product: Advantage® 10 Advantage® 20 Advantage® 55 Advantage® 100		Ingredient: Imidacloprid, CAS = 138261-41-3	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Report Number Description

84-2(a)	Gene mutation (ames test)	42256341	264	PER	Report No. 101276	
		42256342	264	PER	Report No. 98584	
		42256343	264	PER	Report No. 98570	
84-2(b)	Structural chromosomal aberration	42256344	264	PER	Report No. 100021	
		42256345	264	PER	Report No. 99262	
		42256346	264	PER	Report No. 99257	
		42256347	264	PER	Report No. 102652	
		42256348	264	PER	Report No. 102654	
84-4	Other genotoxic effects	42256349	264	PER	Report No. 102655	
		42256350	264	PER	Report No. 99676	
		42256351	264	PER	Report No. 101275	
		42256352	264	PER	Report No. 98573	
85-1	General metabolism	42256353	264	PER	Report No. 102653	
		42256354	264	PER	Report No. 101999	
		42256355	264	PER	Report No. 87264	
		42256356	264	PER	Report No. 87265	
8707200 (86-1)	Domestic Animal Safety	42256357	264	PER	Report No. 102617	
		43679607	11556	OWN	Report No. 74580	Dogs
		43679608	11556	OWN	Report No. 74590	Dogs
		44099801	11556	OWN	Report No. 74730	Puppies



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Report Number Description

95-9	Efficacy	43679503	11556	OWN	Report No. 74571	Cats
		43679504	11556	OWN	Report No. 74581	Cats
		43679609	11556	OWN	Report No. 74572	Dogs
		43679610	11556	OWN	Report No. 74541	Dogs
		44256901	11556	OWN	Report No. 74800	Speed of flea kill
		44256902	11556	OWN	Report No. 47828	Larvicidal efficacy
		44256903	11556	OWN	Report No. 74792	Effects of shampooing
		47109101	11556	OWN	Report No. 75867 (K9)	Waterproof
		47298201	11556	Own	Report No. 75867-1 (K9)	Waterproof – Protocol & Raw Data
		45425101	11556	OWN	Report No. 75292	Cats
		45425102	11556	OWN	Report No. 75293	Cats
		47190401	11556	OWN	Report No. 75950	Lice
Plant Protection, Section 158.540						
122-2	Aquatic plant growth					N.A.
123-2	Aquatic plant growth					N.A.
Non-Target Insects, Section 158.590						
141-1	Honey bee acute contact					N.A.
141-2	Honey bee residue on foliage					N.A.



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Bayer HealthCare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390			Product:		Advantage® 10 Advantage® 20 Advantage® 55 Advantage® 100		Ingredient: Imidacloprid, CAS = 138261-41-3
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note Report Number		Description

Reentry Protection,
Section 158.390

230-236	Mixer/loader/applicator exposure	42256386	264	PER	Report No. 94273
		43790701	11556	OWN	Report No. 106743

Environmental Fate,
Section 158.290

161-1	Hydrolysis					N.A.
161-2	Photodegradation - water					N.A.
161-3	Photodegradation - soil					N.A.
162-1	Aerobic soil metabolism					N.A.
162-2	Anerobic soil metabolism					N.A.
162-3	Anaerobic aquatic metabolism					N.A.
163-1	Leaching / adsorption/desorption					N.A.
164-1	Terrestrial field dissipation					N.A.
165-1	Confined rotational crop					N.A.
165-2	Field rotational crop					N.A.
166-1	Groundwater small prospective					N.A.
None	Environmental fate summary					N.A.

00-61-20



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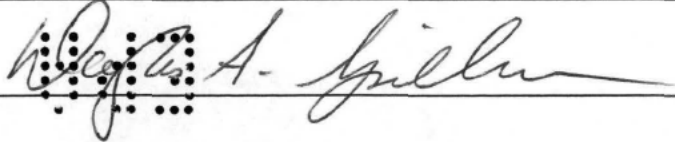
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Report Number

Residue, Section 158.240						
171-4(a)	Nature of residue - plants					N.A.
171-4(b)	Nature of residue - livestock and poultry					N.A.
171-4(c)	Residue analytical method - plants					N.A.
171-4(d)	Residue analytical method - animal					N.A.
171-4(e)	Storage stability					N.A.
171-4(j)	Magnitude of residues - meat/milk/poultry/egg					N.A.
171-4(k)	Magnitude of residue - crop field trials					N.A.
171-4(l)	Magnitude of residue - processed food/feed					N.A.
171-4(m)	Method validation/ multiresidue method					N.A.
None	Benefits Reports					
None	Dietary Analysis					N.A.

Signature 	Douglas A. Spilker Manager, EPA Regulatory Affairs	February 15, 2008
-----------------------------------------------------------------------------------------------	-------------------------------------------------------	-------------------

00.61.20

Fee for Service

{824783B~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 1

Receipt No.

S-

824783

EPA File Symbol/Reg. No.

11556-117

Pin-Punch Date:

2/19/2008

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ ____

Parent/Child Decisions:

Non-fee

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer:

VMMR Eagle

Date:

2/20/08

Remarks:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 21, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

TERRY MCNAMARA
BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION
PO Box 390
SHAWNEE MISSION, KS 66201-0390

PRODUCT NAME: ADVANTAGE TM 10 (IMIDACLOPRID) TOPICAL SOLUTION
COMPANY NAME: BAYER HEALTHCARE LLC
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 11556-117
EPA RECEIPT DATE: 02/19/08

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 1, at (703) 308-8045.

Sincerely,
Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

FAST-TRACK AMENDMENTS-Completeness Screening Checklist

Experts In-Processing Signature: 

IRB.

EPA Reg. Number: 11556-117

EPA Receipt Date: 2/19/08

	Check List Item	Yes	No	NA
1	Application Form (EPA Form 8570-1) -signed?	✓		
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?			✓
3	Certification with Respect to Citation of Data (EPA Form 8570-34) signed?	✓		
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?			✓
5	Data Matrix (EPA Form 8570-35) [Applicable, for adding me-too uses]			
	a) Selective Method?	✓		
	b) Cite-All Method? Applicant owns data or list only the companies offered to pay			
	c) Public copy of Matrix provided? See PR Notice 98-5	✓		
6	Is Label Included? (5 copies)	✓		
	Comments:			

MATERIAL TO BE ADDED TO JACKET

REG #

11556-117

Description:

check all that apply

☐

new stamped accepted label

☐

new CSF

☒

notification

Send to CSC

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's
Name:

Joyce Edwards
308-5479

Date:

9-24-07

Phone:

Division:

RD



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SEP 24 2007

Mary McKinney Hunt
Pesticide Regulatory Manager
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

RE: Proposed Label Revision, to remove the word "only" from a proposed statement
EPA Reg. No.: 11556-117
Date of Submission: September 10, 2007

Dear Ms. Hunt:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated September 10, 2007, for the product Advantage 10 Topical Solution. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely,

Rachel C. Halloman
for Linda Arrington

Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

Registration
Amendment
Other**OPP Identifier Number**

Application for Pesticide - Section I

1. Company/Product Number 11556-117	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Advantage 10 Topical Solution	PM# Team 1	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/>	Amendment - Explain below.	<input type="checkbox"/>	Final printed labels in response to Agency letter dated _____	NOTIFICATION SEP 24 2007
<input type="checkbox"/>	Resubmission in response to Agency letter dated _____	<input type="checkbox"/>	"Me Too" Application.	
<input checked="" type="checkbox"/>	Notification - Explain below.	<input type="checkbox"/>	Other - Explain below.	


Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Enclosed for Agency acceptance is the draft label for Advantage 9 Topical Solution (EPA Reg. No. 11556-116). The only label revision is the removal of the word, "only," in the following statement: Available "only" through licensed practicing veterinarians. The proposed statement is: "Available through licensed practicing veterinarians." Please see attachment for further detail.

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt No. per container	
2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____					
3. Location of Net Contents Information		4. Size(s) Retail Container		5. Location of Label Directions	
<input type="checkbox"/> Label <input type="checkbox"/> Container				<input type="checkbox"/> _____	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point <i>(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</i>		
Name Mary McKinney Hunt	Title Pesticides Regulatory Manager	Telephone No. (Include Area Code) (913) 268-2311
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		5. Date Application Received (Stamped)
2. Signature 	3. Title Pesticide Regulatory Manager	
4. Typed Name Mary McKinney Hunt	5. Date Sept 10, 2007	

SEP 24 2007

ATTACHMENT FOR OPP
APPLICATION FOR PESTICIDE NOTIFICATION
Page 1 of 1

Advantage 10 Topical Solution, EPA Reg. No. 11556-117
September 10, 2007

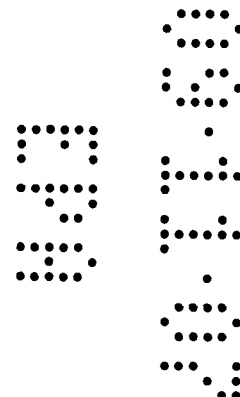
Enclosed for Agency acceptance is a draft label for Advantage 10 Topical Solution, EPA Reg. No. 11556-117.

The only proposed change is the removal of the word, "only."

from: Available only through licensed practicing veterinarians.

to: **Available through licensed practicing veterinarians.**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.



MAR 10 2006

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for this pesticide
Registered under
EPA Reg. No. 11556-117

advantage®

(imidacloprid)
Topical Solution

10

Once-a-month topical flea treatment for dogs and puppies
7 weeks and older and 10 lbs. and under.

NOTIFICATION

READ THE ENTIRE LABEL BEFORE EACH USE.

For the Prevention and Treatment of Flea Infestations on Dogs

- Available through licensed practicing veterinarians
- Kills 98-100% of the fleas on dogs within 12 hours
- One treatment prevents further flea infestation for at least four weeks
- Kills fleas before they lay eggs

SEP 24 2007

Active Ingredient

Imidacloprid; 1-[(6-Chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine

% By Weight

Other Ingredients

9.1%

Total

90.9%

100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING

See below for First Aid and Precautionary Statements.

Precautionary Statements

Hazards to Humans: Causes eye irritation. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling. Keep out of reach of children. Do not contaminate feed or food.

Hazards to Domestic Animals

For external use only. Do not use on puppies under seven weeks of age. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product. For consumer questions call 1-800-255-6826. For medical emergencies call 1-877-258-2280.

First Aid

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If swallowed: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

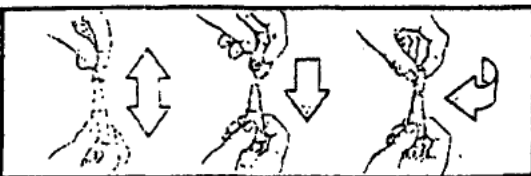
To Physician: Treat the patient symptomatically.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

How to Apply

- Use only on dogs. Do not use on other animals.
- Remove one applicator tube from the package.



Bayer HealthCare

Manufactured For Bayer HealthCare LLC, Animal Health Division,
Shawnee Mission, Kansas 66201 USA

Bayer, the Bayer Cross and Advantage are trademarks of Bayer

Advantage is protected by one or more of the following U.S. patents: 6,836,462, 6,813,783,
6,486,573, 6,379,374, 6,232,376, 6,418,032, 6,298,607, 6,204,380, 6,478,080

- Hold applicator tube in an upright position. Pull cap off tube.
- Turn the cap around and place other end of cap back on tube.
- Twist cap to break seal, then remove cap from tube.



- The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube twice to expel the entire contents of the tube directly on the skin. Do not get this product in your pet's eyes or mouth.
- Discard empty tube as described in Storage and Disposal.

The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with Advantage rapidly kills fleas and may reduce the incidence of this condition.

Advantage kills 98-100% of the fleas on pets within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for up to four (4) weeks. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.

Larval flea stages in the pet's surroundings are killed following contact with an Advantage treated pet.

Advantage remains efficacious following a shampoo treatment, swimming or after exposure to rain or sunlight.

Monthly treatments are required for optimal control and prevention of fleas.

If re-treatment becomes necessary earlier than four weeks, do not re-treat more than once weekly.

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a cool, dry place.

Disposal: If empty: Do not reuse container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 1-877-258-2280 for disposal instructions. Never place unused product down any indoor or outdoor drain.

Limited Warranty and Limitation of Damages

Bayer HealthCare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label. BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing without specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

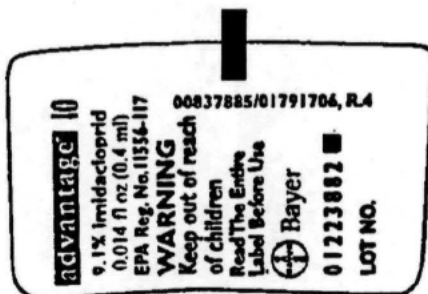
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Made in Germany

00837885-032800/01701708-053888

• • • • • EPA Reg. No. 11556-117

To receive monthly email application reminders, go to www.noiflms.com



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